

EDITORIAL COMMENT

Radial Artery Access in Women Undergoing Percutaneous Coronary Procedures*



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Complications of vascular access are common after diagnostic coronary angiography and percutaneous coronary intervention (PCI), and include bleeding from the arterial access site, hematoma and pseudoaneurysm formation, and retroperitoneal hemorrhage (1). These complications are uncomfortable, often extend hospital stay, and can result in potentially dangerous interruption of antiplatelet medications, transfusion of blood products, and subsequent peripheral vascular procedures that carry their own inherent risks. As a result, patients who experience bleeding following PCI have an increased risk of death, with hazard ratios for death increasing from 1.7 to 4.9 with increasing severity of bleeding (2). Identifying ways to decrease vascular complication rates and bleeding in patients undergoing coronary angiography and PCI is, therefore, important.

There is a paucity of data regarding clinical outcomes of women undergoing PCI (3), but it is known that, compared with men, women are at a particularly high risk of access site complications following PCI (1,3-5). Previous studies suggest that the use of radial access for PCI reduces bleeding risk in both men and women (5,6). Radial artery access, however, is technically more challenging in women because of smaller caliber radial arteries and increased rate of radial artery spasm (7), resulting in frequent procedure failure

and crossover to the femoral approach (8). In this context, the SAFE-PCI (Study of Access Site for Enhancement of PCI for Women) trial (9) compared radial and femoral artery access in women undergoing procedures either electively or for non-ST-segment elevation myocardial infarction (STEMI): the crossover rate from radial to femoral access was 6.7%. The study was terminated early because of lower than expected rates of bleeding and vascular complications. There was no significant difference in access site complication rates in the PCI subgroup, although there was a significant decrease in bleeding and vascular complications using the radial approach in the entire cohort.

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The study by Pandie et al. (10), published in this issue of *JACC: Cardiovascular Interventions*, provides additional data on the efficacy and safety of radial access in women. This study is a pre-specified subgroup analysis of the randomized, multicenter RIVAL (Radial Versus Femoral Access for Coronary Intervention) trial (11). In the parent trial, 7,021 patients referred for coronary angiography for acute coronary syndrome were randomized to radial versus femoral artery access. The present analysis focuses on differences in outcomes between the 1,861 women and 5,160 men enrolled in the trial. Women were twice as likely to be crossed over to femoral access compared with men (11.1% in women and 6.3% in men). The most common reason for this was a higher rate of radial artery spasm (9.5% in women vs. 3.3% in men; $p < 0.001$). PCI was equally successful in women and men, irrespective of access site. Overall rates of major vascular complications were higher in women (4.7% vs. 1.7%; $p < 0.0001$), with other predictors of vascular complications including age, performance

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of PCI, and use of glycoprotein IIb/IIIa inhibitors. Importantly, major vascular complications were significantly reduced with the use of radial access in both sexes, but this effect was more prominent among women, irrespective of whether PCI was performed. The number of patients needed to treat with radial access instead of femoral access to prevent 1 vascular complication was 33 in women and 49 in men. These data suggest that women undergoing coronary angiography for acute coronary syndrome may particularly benefit from the radial approach.

These results should be considered in the context of several caveats. First, the parent study was not powered to assess differences between sexes and randomization was not stratified according to sex. Hence, it is possible that selection bias played a role in recruiting specific women (such as those with strong radial pulses) into the trial; such a bias would limit the applicability of these results to all women undergoing angiography. Second, the present study does not address experience of the operator with the radial technique. This may be important because in the parent trial (11), the radial approach was shown to be superior to the femoral approach only if performed by operators most experienced with the radial approach. Third, the influence of choice of pharmacotherapy on vascular access site complications is not addressed by the present study, which left this choice

to the operator's discretion. Specifically, the majority of patients were treated with heparin (82% of women and 85% of men) and glycoprotein IIb/IIIa inhibitors (19% of women and 27% of men) as compared with bivalirudin (2.4% of women and 2.7% of men). Because bivalirudin, a direct thrombin inhibitor, has been shown to decrease bleeding in patients undergoing PCI (12), it is possible that the use of bivalirudin would negate the effect of vascular access site.

The current study suggests that radial access is an effective technique to reduce vascular complications in women undergoing coronary angiography and PCI if performed by experienced operators. The on-going SAFARI-STEMI (Safety and Efficacy of Femoral Access Versus Radial for Primary Percutaneous Coronary Intervention in ST-Elevation Myocardial Infarction) trial (NCT01398254) is randomizing men and women presenting with STEMI to radial versus femoral access and mandating that all patients receive bivalirudin. This study should help to tease out the relative effect of access site and choice of pharmacotherapy on bleeding complications in high-risk men and women undergoing PCI.

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